



UNITED STATES PATENT AND TRADEMARK OFFICE

AUG -2 2004

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

4150 04 SEP -1 21:33

Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention: Claudia Grillo

Dear Ms. Axelrad:

The attached application for patent term extension of U.S. Patent No. 4,937,078 was filed on June 7, 2004, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, SURPASS® (diclofenac sodium), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first permitted commercial marketing or use in animals, and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Paul E. Dietze
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Ave. NW
Washington DC 20004

2004E-0389

LET 1